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By: Spencer

PATENT
Attorney Docket No. 018563-006700US
Client Ref. No. 9047.ALG.US.P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ERIC KUO

Application No.: 10/612,239

Filed: July 1, 2003

For: DENTAL APPLIANCE
SEQUENCE ORDERING SYSTEM
AND METHOD

Confirmation No. 3324

Examiner: WILSON, JOHN J.

Technology Center/Art Unit: 3732

APPELLANT'S BRIEF UNDER
37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal mailed on August 10, 2007, for the above-referenced application, Appellant submits this Brief on Appeal.

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1. REAL PARTY IN INTEREST

All right, title, and interest in the subject invention and application is assigned to Align Technology, Inc., having offices at 881 Martin Avenue, Santa Clara, California 95050. Therefore, Align Technology, Inc. is the real party in interest.

2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1, 19-21, 27-29, and 37-48 are currently pending. Claims 2-18, 22-26, and 30-36 have been canceled. Currently pending claims 19-21, 27-29, and 37-48 stand rejected under 35 U.S.C. §103(a), with claims 45-46 standing further rejected under 35 U.S.C. §112, first paragraph. Currently pending claims 19-21, 27-29, and 37-48 are the subject of this appeal. No other claims are pending.

Claim 47 was previously rejected under 35 U.S.C. §112, first paragraph, in the Office Action mailed February 13, 2007; however, as indicated by the Advisory Action mailed July 6, 2007, this rejection was overcome by Appellant's response mailed June 13, 2007.

4. STATUS OF AMENDMENTS

A Final Office Action was mailed on February 13, 2007, in which: 1) claims 1, 14-16, 19-21, and 27-48 were pending; 2) claims 14-16, 19-21, 27-36, and 38-48 were rejected under 35 U.S.C. §103(a); 3) claims 45-47 were rejected under 35 U.S.C. §112, first paragraph; and 4) claims 1 and 37 were allowed.

On June 13, 2007, appellant submitted an amendment under 37 C.F.R. §1.116 seeking to amend claims 14, 19, 27, 30, 38, 40, 44, and 47. The submitted amendments to claims 14, 19, 27, 30, 38, 40, 44, and 47 were denied entry as set forth in the Advisory Action mailed July 6, 2007. The rejection of claim 47 under 35 U.S.C. §112, first paragraph, was withdrawn in the Advisory Action mailed July 6, 2007.

In response to the Advisory Action mailed July 6, 2007, appellant submitted a second amendment under 37 C.F.R. §1.116 seeking to cancel claims 14-16 and 30-36 in order to narrow the issues under review/appeal. An Advisory Action mailed August 7, 2007, indicated that the amendment canceling claims 14-16 and 30-36 was entered.

A Pre-Appeal Brief Request for Review, in conjunction with a Notice of Appeal, was filed on August 10, 2007. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed on September 13, 2007, indicating the application remains under appeal, with claims 1 and 37 allowed and claims 19-21, 27-29, and 38-48 rejected.

As such, claims 1, 19-21, 27-29, and 37-48 are currently pending. A copy of all the pending claims involved in the appeal is provided in the Claims Appendix, attached hereto.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides systems and methods for providing dental appliances, particularly orthodontic appliances, to a patient wherein the patient is easily able to determine the order or sequence in which the appliances should be worn. U.S. Application No. 10/612,239, filed July 1, 2003 (hereinafter "Application"), page 3, lines 10-12.

Independent claim 1 is directed to a system of polymeric shell dental appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where at least some of the appliances (10) include a non-numeric indicia designating the order in which the appliances (10) are used with the indicia comprising a terminal tooth cavity (40a; 40b) of differing length. These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 8, lines 1-12; Figures 1, 4A, and 4B.

Independent claim 19 is directed to a system of dental appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement; a framework (20) wherein dental appliances (10) are removably attached to a portion of the framework (20); and a non-numeric indicia designating the order in which the appliances (10) are used. These elements are discussed in the Application, for example, at least at page 4, lines 14-21; page 7, lines 16-24; Figure 2.

Independent claim 27 is directed to a package of geometrically distinct dental appliances (10) having cavities shaped to receive and reposition teeth from one arrangement to a successive arrangement; the appliances (10) positioned in an arrangement within the package (12 and 30) which indicates an order of use. These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 7, lines 25-34; page 10, line 30 through page 11, line 2; Figures 3 and 11.

Independent claim 37 is directed to a system of polymeric shell dental appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where at least some of the appliances (10) include a non-numeric indicia designating the order in which the appliances (10) are used with the indicia comprising a different height in each of the polymeric shells (10a and 10b). These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 8, lines 12-19; Figures 5A and 5B.

Independent claim 38 is directed to a system of polymeric shell appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where at least some of the appliances (10) include a non-numeric indicia designating the order in which the appliances (10) are used with the indicia comprising one or more cutouts (56) so that each polymeric shell (10) has a different cutout pattern (56a and 56b). These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 8, lines 20-29; Figures 6A and 6B.

Independent claim 40 is directed to a system of polymeric shell appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where at least some of the appliances (10) include a non-numeric indicia designating the order in which the appliances (10) are used with the indicia comprising a computer readable element (100). These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 10, lines 3-8; Figure 9.

Independent claim 44 is directed to a system of dental appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where the appliances (10) comprise a color indicia (60a and 60b) designating the

order in which the appliances (10a and 10b) are used with the color indicia (60a and 60b) comprising a dissolvable dye. These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 8, line 30 through page 9, line 18; Figures 7A, 7B, and 7C.

Independent claim 47 is directed to a system of dental appliances (10) having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, where the appliances (10) comprise a color indicia designating the order in which the appliances (10) are used with the color indicia comprising a peel-away wrapper (62) removably attached to an appliance. These elements are discussed in the Application, for example, at least at page 3, lines 10-21; page 9, lines 13-18; Figure 7C.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Rejections Under 35 U.S.C. §112

Whether claims 45 and 46 were properly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

Rejections Under 35 U.S.C. §103

Whether claims 19-21 and 48 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Klein (U.S. Patent no. 4,038,753).

Whether claims 27-29 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Klatt (U.S. Pub. No. 2003/0136698).

Whether claims 38 and 39 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Rohlcke *et al.* (U.S. Patent No. 5,326,259).

Whether claims 40 and 41 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Martin (U.S. Patent No. 6,884,071).

Whether claims 42 and 43 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) and Martin (U.S. Patent No. 6,884,071) as applied to claim 40 above, and further in view of Morris *et al.* (U.S. Patent No. 5,923,001).

Whether claims 44 and 47 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695).

Whether claims 45 and 46 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti *et al.* (U.S. Patent No. 5,975,893) in view of Wong *et al.* (U.S. Patent No. 6,206,695) as applied to claim 44 above, and further in view of Bates *et al.* (U.S. Patent No. 5,411,295).

7. ARGUMENT

I. The rejection of claims 45 and 46 under 35 U.S.C. §112, first paragraph, for lack of enablement should be reversed for lack of a reasonable basis to support a determination that undue experimentation would be required.

Claims 45 and 46 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

It is alleged that claims 45 and 46 lack enabling support in the originally filed disclosure for the claim elements including a "dissolvable dye". Appellant submits, however, that this rejection should be reversed because the Examiner has failed to establish a reasonable basis to support an alleged lack of enabling disclosure in the application as filed. The only basis cited by the Examiner for the rejection is a lack of working examples in the specification, which without more is insufficient to support the alleged lack of enablement. As set forth below, there is no reason to expect that undue experimentation would be required to make or use the system of claim 45 or 46, e.g., by selecting a dissolvable dye among available or known dissolvable dyes.

In the present case, the sole basis for rejecting claims 45 and 46 as allegedly lacking enabling disclosure in the specification was an absence of specific working examples of dissolvable dyes identified in the application. In particular, the Examiner alleged that "[n]o examples of color indicia comprising a dissolvable dye that dissolves in water or one that dissolves in air has been given, thus requiring one of ordinary skill in the art to engage in undue research and experimentation to determine how to make and use the claimed invention" (See, Office Action, mailed 2/13/2007, pages 2-3). As Appellant has previously pointed out, however, merely citing a lack of working examples is insufficient to support an alleged case of lack of enabling disclosure.

"The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telecommunications, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). While disclosure of working examples is one factor that supports enabling disclosure, it is well established that a lack of working examples is not dispositive with respect to the enablement issue. As set forth in MPEP § 2164.02, "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." Further stated, "[i]n other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. MPEP § 2164.02, emphasis added.

Not only is the basis for the rejection improperly limited to a single non-dispositive factor, but the Examiner has offered no explanation why the lack of working examples would result in undue experimentation. Instead of providing an explanation or rationale, only an unsupported assertion have been provided. Appellant submits that such mere conclusory statements are insufficient to support a rejection of lack of enabling disclosure. Appellant further points out that, in order to properly support a rejection, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a

claim is not adequately enabled by the disclosure). MPEP § 2164.04. No such reasonable explanation or rationale has been provided in the present case, indicating that the Office has failed to meet the requisite burden in establishing an alleged lack of enablement.

Nevertheless, despite the deficient rationale/basis for the alleged lack of enablement, Appellant has further pointed out that one skilled in the art viewing the specification would recognize that known/commercially available dissolvable dyes are available for use according to the present invention, and that specifically listing in the specification every dissolvable dye known in the art is neither necessary nor required. (see, e.g., Appellant's response filed 6/13/07). "A patent need not teach, and preferably omits, what is well known in the art." (MPEP § 2164.01). Regarding the level "experimentation", as previously noted, the skilled artisan would recognize that simply choosing a dye from among known/available dissolvable dyes would require no undue experimentation. These remarks by Appellant have not been rebutted by the Examiner.

In the Advisory Action mailed 7/6/2007, rather than rebut Appellant's remarks supporting enabling disclosure, or provide any objective evidence or rationale to support the alleged lack of enablement, the Advisory Action incorrectly reads that "it is [A]pplicant's duty to supply support for the statement that one of ordinary skill in the art [sic] would find a dye to use as claimed without undue experimentation." Appellant respectfully disagrees. First, Appellant has provided remarks supporting enablement of the claims at issue, but the remarks have not been addressed. Second, Appellant submits that it is well established that the Examiner/PTO, not Appellant, bears the initial burden to establish a lack of enablement. See above. See also, MPEP § 2164.04, titled "Burden on the Examiner under the Enablement Requirement". The Examiner's attempt to place the initial burden on the Appellant is a clear error of law. Accordingly, as the Office has failed to meet the initial burden in establishing a rationale/basis for the lack of enablement rejection (e.g., merely citing a lack of working examples in insufficient to establish lack of enablement), Appellant is under no obligation to provide additional evidence.

Although Appellant is under no obligation to provide additional evidence in the present case, even if Appellant wished to provide further support, such as providing objective

evidence of dissolvable dyes generally available to those skilled in the art, Appellant was effectively denied such an opportunity. As previously noted, the rejection was first presented in the Final Office Action in which prosecution was closed. Further, MPEP 2164.04 states:

In accordance with the principles of compact prosecution, if an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments and/or evidence in rebuttal. Providing the best case in the first Office action will also allow the second Office action to be made final should applicant fail to provide appropriate convincing arguments and/or evidence. Citing new references and/or expanding arguments in a second Office action could prevent that Office action from being made final.

In sum, examiner has failed to meet the initial burden of proof regarding lack of enablement. The only support for the alleged lack of enabling disclosure in support of the dissolvable dye aspect of claims 45 or 46 is a lack of working examples listed in the specification. No other evidence or rationale has been provided. However, it is well established that this factor alone cannot support a rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement. Moreover, Appellant's remarks supporting the fact that the original specification would provide enabling disclosure for the dissolvable dye aspect of claims 45 and 46, and indicating a lack of undue experimentation in selecting dissolvable dyes among those known in the art have not been addressed and are unrebutted.

Accordingly, for at least the reasons set forth above, Appellant respectfully requests that these rejections be withdrawn and claims 45 and 46 allowed.

II. The rejection of claims 19-21 and 48 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,975,893 to Chishti et al. in view of U.S. Patent No. 4,038,753 to Klein should be reversed.

Claims 19-21 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,975,893 to Chishti et al. (hereinafter "Chishti") in view of U.S. Patent No. 4,038,753 to Klein (hereinafter "Klein").

The present rejections should be reversed because the references cited by the Examiner, taken either alone or in combination, fail to teach or suggest each element of the claimed invention. In particular, the references at least fail to teach non-numerical indicia designating an order of use, as recited in claim 19. Appellant respectfully disagrees with Examiner's position that the recited element regarding non-numeric indicia designating order of use is of no patentable weight.

The ultimate determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). The underlying factual determinations include: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S. Ct. at 1734, 82 USPQ2d at 1391 (“While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls.”)

The PTO has the initial burden of establishing a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The PTO can satisfy this burden by showing some objective teaching in the prior art which would have led one of ordinary skill in the art to the invention claimed. *Fine*, 837 at 1074, 5 USPQ2d at 1598. “If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.” MPEP § 2142. “Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 127 S.Ct. at 1741 (quoting Federal Circuit statement with approval). All limitations of the claimed invention must be taught or suggested by the prior art to establish obviousness. *In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

In the present case, claims 19-21 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Klein. Independent claim 19, from which claims 20, 21, and 48 depend, reads as follows:

*A system of dental appliances comprising:
a plurality of dental appliances to be worn by a patient to provide
dental treatment, each of the plurality of dental appliances having cavities shaped
to receive and resiliently reposition teeth from one arrangement to a successive
arrangement;
a framework, wherein each of the plurality of dental appliances
are removably attached to a portion of the framework; and
a non-numeric indicia designating an order in which each of the
plurality of dental appliances are to be worn by a patient to provide dental
treatment.*

[Emphasis added].

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the Office has failed to establish that the element of non-numeric indicia designating an order of use, as recited in claim 19, is taught or suggested in the cited references of Chishti or Klein, or anywhere else in the art.

Chishti does not teach each of the recited limitations of independent claim 19. Chishti teaches a system for repositioning teeth including a plurality of individual appliances that are worn by a patient in a designated sequence. While Chishti teaches numerical indicia for order of use, Chishti does not teach any non-numeric indicia designating order of use of a plurality of dental appliances or providing the appliances on a framework with non-numeric indicia, as has been acknowledged by the Examiner. (See Final Office Action mailed 02/13/2007, page 4). As such, Chishti fails to teach or suggest a non-numeric indicia designating an order in which each of the plurality of dental appliances are to be worn by a patient to provide dental treatment as recited in claim 19.

Klein, however, fails to provide the teachings that are missing from Chishti. In particular, nowhere does Klein teach non-numeric indicia designating order of use. Instead, Klein teaches a plurality of identical tension-applying rings (e.g. elastic bands) disposed on a carrier. As taught by Klein, the tension-applying rings of the carrier are designed for conventional orthodontic systems (e.g., traditional orthodontic braces) and are stretched, in no

particular order, over hooks, brackets, etc. of conventional orthodontic appliances (e.g. affixed "braces"). The carrier of Klein is shown with an indicium "A-1-REG.", which appears to designate the particular size of the tension-applying rings disposed on the particular carrier shown.

The Examiner incorrectly cites the term "A-1-REG" as providing "non-numeric indicia" (e.g., as opposed to non-numeric indicia designating order of use, as recited in claim 19) cures the deficiencies of Chishti. First, this term is not even "non-numeric" indicia as required in claim 19, but instead a combination of numeric and non-numeric characters. Second, claim 19 recites non-numeric indicia designating order of use, not just any "non-numeric indicia." As discussed above, the "A-1-REG" term shown does not include information designating any order of use, but instead appears to merely convey information regarding the sizing of the tension rings. The "A-1-REG" term shown actually appears incapable of designating any order of use, and is not associated individually with any particular tension-applying rings. In fact, since all the rings appear identical, order of use would seem completely irrelevant in the teachings of Klein.

Despite the failure of the cited references to teach each of the limitations of independent claim 19, including any non-numeric indicia designating order of use, the Examiner further argues that "the specific meaning of the indicia, is merely a matter of mental interpretation, and/or, intended use, and as such, is properly not given patentable weight." (See Final Office Action mailed 02/13/2007, page 4). As Appellant interprets Examiner's remarks, the Examiner appears to agree that the "indicia" of Klein ("A-1-REG") include no designation of order of use, but it is alleged that only the term "non-numeric indicia" is attributed any patentable weight. In other words, the element of claim 19 requiring that the non-numeric indicia include information designating order of use is allegedly attributed no patentable weight as merely stating intended use or mental interpretation of a structure recited in the claim ("non-numeric indicia"). Appellant respectfully disagrees.

At the outset, Appellant agrees that, as a general matter of law, merely reciting an intended use of a claimed device may not limit the scope of the claim. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); *see also Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345, 65 USPQ2d 1961, 1965 (Fed. Cir. 2003)

("An intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates.").

Appellant respectfully submits, however, that this principle is misplaced here because Appellant is not merely defining a context in which the claimed system operates, but is instead structurally defining the claimed invention. Referring to the language of claim 19, the non-numeric indicia element as recited necessarily designates order of use. One of ordinary skill would recognize that such information/designation is defined by the structure of the indicia itself, and that not every non-numeric indicia includes information designating order of use. In fact, many conceivable non-numeric indicia would actually be completely devoid of any information that designates order of use, as illustrated by the Klein reference itself. Referring to Klein, no reasonable mental interpretation of the term "A-1-REG" as recited in Klein would designate order of use of anything (particularly not identical oral tension rings with which order of use is irrelevant), and the term would actually appear completely incapable and useless for this purpose. Accordingly, Appellant respectfully submits that there is simply no basis by which to ignore the recited element regarding designation of order of use.

In sum, for the reasons set forth above, the claimed invention is not taught or suggested in the cited references or elsewhere, thereby precluding a *prima facie* case of obviousness. The cited references, taken alone or in combination, would at least fail to teach non-numeric indicia designating order of use, as recited in claim 19.

Accordingly, Appellant respectfully requests that the rejection of claims 19-21 and 48 under 35 U.S.C. §103(a) as obvious be reversed, and claims 19-21 and 48 allowed.

III. The rejection of claims 27-29 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of U.S. Pub. No. 2003/0136698 to Klatt should be reversed.

Claims 27-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of U.S. Pub. No. 2003/0136698 to Klatt (hereinafter "Klatt").

Independent claim 27, from which claims 28, and 29 depend, reads as follows:

*A package of dental appliances comprising:
a package including a plurality of geometrically distinct dental
appliances positioned in an arrangement within the package which indicates an
order of usage, the plurality of dental appliances comprising a plurality of
geometrically distinct successive appliances having cavities and wherein the
cavities of successive appliances have different geometries shaped to receive and
reposition teeth from an initial arrangement toward a successive arrangement.
[Emphasis added].*

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the Office has failed to establish that the element of a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package which indicates an order of usage, as recited in current claim 27, is taught or suggested in the cited references of Chishti or Klatt, or anywhere else in the art.

Chishti does not teach each of the recited limitations of independent claim 27. As discussed above, while Chishti teaches numerical indicia for order of use, Chishti does not teach non-numerical indicia designating order of use, such as providing the appliances in a package in an arrangement designating order of use, as has been acknowledged by the Examiner. (See Final Office Action mailed 02/13/2007, page 5).

Klatt, however, fails to provide the teachings that are missing from Chishti. In particular, nowhere does Klatt teach a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package which indicates an order of usage.

Klatt teaches a stack of identical (e.g., not geometrically distinct) blister cards in a package with numerical indication of the number of days left in a drug treatment regime. The stacking of Klatt is taught for the purpose of visualizing length of treatment and drug regime duration, with no indicia or information indicating order of use. While a particular order of use might be incidental once the blister cards are stacked and then consistently drawn from the bottom of the stack, no particular ordering or staking is taught by Klatt. In fact, as the blister

cards of Klatt are identical, order of usage would be irrelevant to the system of Klatt. Stacking according to Klatt would appear to be random. Thus, Klatt fails to teach geometrically distinct articles/appliances positioned in an arrangement within the package, the positioning having information which indicates an order of usage.

The Examiner disregards the distinction that Klatt teaches stacking identical objects (e.g., blister cards) compared to positioning of geometrically distinct dental appliances, and alleges in the Final Office Action 2/13/2007 (page 5) that the term "geometrically distinct" is not defined by the present disclosure, and further points out that the blister cards of Klatt are geometrically located in different locations. Appellant respectfully submits that the Examiner's position has no reasonable basis as the Examiner's claim interpretation would be precluded by the plain meaning of the term "geometrically distinct appliance", which clearly does not refer to relative positioning of different objects or the obvious fact that two different objects cannot occupy the same space at the same time. Appellant also points out that the term "geometrically distinct" is further given meaning within the context of its usage in independent claim 27, where the term is used in association with "successive appliances having cavities and wherein the cavities of successive appliances have different geometries ..."

Even if, for arguments sake only, one of ordinary skill were to attempt to combine the teachings of Chishti with those of Klatt, the combined teachings would still fail to teach the claimed invention, including a package including a plurality of geometrically distinct dental appliances positioned in an arrangement within the package which indicates an order of usage, as recited in claim 27. As noted above, Klatt teaches stacking of identical blister cards for visualization of treatment duration. While order of usage may be incidental in Klatt as the patient draws blister cards from the bottom of a stack, the stacking of blister cards would appear to be random, as would be consistent with the use of identical cards as well the disregard in Klatt of any ordering of usage. Thus, even if Klatt were hypothetically combined with Chishti, the proposed combination would, at best, produce a stack of randomly arranged dental appliances with no particular order prescribed by the random stacking. Only the current specification (i.e., impermissible hindsight) would teach stacking or arranging dental appliances in an arrangement that indicates order of use.

In sum, for the reasons set forth above, the Office has not established that the claimed invention is taught or suggested in the cited references or elsewhere, thereby precluding a *prima facie* case of obviousness. The cited references, taken alone or in combination, would at least fail to teach non-numeric indicia designating order of use, as recited in claim 27.

Accordingly, Appellant respectfully requests that the rejection of claims 27-29 under 35 U.S.C. §103(a) be reversed, and claims 27-29 allowed.

IV. The rejection of claims 38 and 39 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong et al. (U.S. Patent No. 6,206,695) and Rohlcke et al. (U.S. Patent No. 5,326,259) should be reversed.

Claims 38 and 39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of U.S. Patent No. 6,206,695 to Wong et al. (hereinafter "Wong") and U.S. Patent 5,326,259 to Rohlcke et al. (hereinafter "Rohlcke").

Independent claim 38, from which claim 39 depends, reads as follows:

*A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern.*

[Emphasis added].

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the Office has failed to establish that the element of a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn, wherein the indicia comprises one or more cutouts so

that each polymeric shell has a different cutout pattern, as recited in claim 38, is taught or suggested in the cited references of Chishti, Wong, or Rohlcke, or anywhere else in the art.

Chishti is overcome for at least a similar rationale as set forth above. While Chishti teaches numerical indicia for order of use, Chishti does not show using a non-numeric indicia designating order of use, as has been acknowledged by the Examiner. (See Final Office Action mailed 02/13/2007, page 7).

Appellant respectfully disagrees that Wong teach color (i.e., colored handles) to indicate order of usage of orthodontic reamers, as alleged in the Final Office Action, mailed 2/13/07 (page 7). Wong teaches orthodontic reamers with colored handles, but the different colored handles are designed to allow the practitioner to more easily distinguish the differently sized endodontic reamers and avoid confusion between different sized reamers that may be otherwise difficult to distinguish upon visual inspection. No specific order of use of the tools is prescribed by the color designations. The mere fact that a practitioner may use progressively larger sized reamers in performing a root canal does not provide the teaching of using a color scheme as an indication for order of usage. No specific starting (e.g., first) reamer or finishing/final reamer, or even that a practitioner must strictly adhere to using a specific sequence of reamers, is prescribed by the colored handles, or otherwise taught in Wong. Such an interpretation, it is submitted, would appear to be improperly reading teachings into the reference that are not actually provided by Wong, but only provided by Appellant's disclosure.

Appellant points out that while Wong discusses the well-known International Standard Organization (ISO) system that establishes industry manufacturing standards for endodontic instruments (i.e., endodontic reamers or files) used in performing a root canal operation, the ISO standardization system has nothing to do with prescribing order of use of dental appliances or any dental tool. The ISO industry manufacturing standards (e.g., ISO Standard No. 3630) for the endodontic reamers defines factors such as shapes, profiles, lengths, sizes, acceptable manufacturing tolerances, and minimum requirements of mechanical stress, in order to insure uniformity across the dental industry. Pursuant to ISO Standard No. 3630, the endodontic reamers are available in standard sizes defined by the diameter of the working tip, and the standard tip diameter of each reamer corresponds to the number used to identify it .

However, the incrementally sized reamers are difficult to identify simply by looking at the tip diameters, and observation of small printed numbers is frequently obscured during an endodontic procedure by materials or the dentist's fingers (see, e.g., Wong at col. 3, lines 60-63). As such, ISO Standard No. 3630 also establishes a standard color scheme for the endodontic reamer handles, so that reamers with different tip diameters can more easily be distinguished. Thus, the ISO industry standard manufacturing color scheme is designed and used to more easily distinguishing differently sized endodontic reamers, and not in prescribing a specific order of use of the tools.

The mere fact that a dentist performing a root canal procedure, in general, may use progressively larger reamers does not provide the teaching of using a color scheme to designate a specific order of use of dental appliances. On the contrary, one of ordinary skill in the art would recognize that each reamer used at each step of a root canal procedure is selected at the discretion of the dentist and will be based on clinical factors such as age of the patient, disease progression, tooth structure, X-ray data, and the like. Nothing in the ISO industry manufacturing standards prescribes any particular order of use of the endodontic reamers in a root canal procedure. Wong does not teach a starting (e.g., first) reamer, or a finishing/final reamer, or even that a practitioner must adhere to using a specific sequence of reamers. As such, Wong does not provide the teachings that are missing from Chishti - e.g., non-numeric indicia designating an order of use.

Similar to Chishti and Wong, the reference of Rohlcke also fails to teach non-numeric indicia designating an order of use. Rather than teach any indicia designating order of use, Rohlcke teaches marking metal orthodontic brackets, e.g., with a notch, to identify their orientation (e.g., top side, bottom side) when attached to individual teeth. No marking or indicia is taught by Rohlcke as having information regarding order of use. Rohlcke adds little, if anything, to the teachings of Chishti and Wong.

In fact, the Examiner does not even allege that Rohlcke teaches indicia designating order of use, but instead states that "Rohlcke teaches that a notch may be used as an alternative indicia, column 1, lines 21-24." (Final Office Action 2/13/2007, page 7; emphasis added). However, merely providing "indicia" does not satisfy the requirement that the prior art

teach or suggest each element of the claimed invention. Claim 38 recites, *inter alia*, "a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn..., wherein the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern." The teachings of Rohlcke (e.g., a notch indicating bracket orientation) simply do not provide this element of the claimed invention.

Appellant is unclear regarding any rationale as to why one of ordinary skill would combine the cited references in the first place, and certainly no explanation has been provided in the Office Action why the references would be combined or how the proposed combination could actually arrive at the claimed invention. In fact, no logical connection would appear to exist between the teachings of Rohlcke (e.g., markings for bracket orientation) and Wong (e.g., handle color to indicate reamer size). While Wong teaches colored handles and Rohlcke bracket notches, each indicia provide unrelated information and neither reference teaches color or any non-numeric indicia whatsoever including information designating order of use of anything. As such, the cited references fail to teach non-numeric indicia designating an order in which dental appliances are to be worn by a patient, the indicia comprising one or more cutouts so that each polymeric shell has a different cutout pattern, as recited in claim 38.

For the reasons discussed above, Appellant respectfully disagrees with Examiner's position that Wong teaches non-numeric indicia, e.g., color, designating order of use. While Rohlcke teaches notches in brackets indicating bracket orientation, Rohlcke does not teach the claimed non-numeric indicia designating an order of use, including cutouts in a polymeric shell. The cited references, taken either alone or in combination, simply fail to teach or remotely suggest the invention as recited in claim 38, thereby precluding a *prima facie* case of obviousness.

Accordingly, Appellant respectfully submits that the rejection of claims 38-39 under 35 U.S.C. §103(a) as obvious should be reversed, and claims 38-39 allowed, because the presently claimed invention cannot be obtained by combining the teachings of Chishti, Wong, and Rohlcke.

V. The rejection of claims 40 and 41 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong and U.S. Patent No. 6,884,071 to Martin should be reversed.

Claims 40 and 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong and U.S. Patent No. 6,884,071 to Martin (hereinafter "Martin").

Independent claim 40, from which claim 41 depends, reads as follows:

*A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises a computer readable element.*

[Emphasis added].

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the Office has failed to establish that the element of a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn, wherein the indicia comprises a computer readable element, as recited in claim 40, is taught or suggested in the cited references of Chishti, Wong, or Martin, or anywhere else in the art.

As discussed above in connection with the rejection of claims 38 and 39, neither Chishti or Wong, alone or in combination, teach or suggest the use of non-numeric indicia designating order of use, nor do either teach anything regarding non-numeric indicia designating order of use comprising a computer readable element. As indicated above, Examiner has recognized that Chishti does not teach the use of non-numeric indicia indicating order of use and Appellant respectfully asserts that the allegation is incorrect that Wong teaches any non-numeric indicia, specifically color, designating order of use.

Martin does not provide the teachings that are missing from Chishti and Wong. Martin teaches electronically legible codings (bar codes) containing information about the mixing time, the material, the manufacturer and/or the expiration date (see, Martin at col. 7, lines 28-29). Martin fails to teach non-numeric indicia having coding, embedded instructions, or any other structure including information regarding order of use. As such, neither Chishti, Wong nor Martin teaches non-numeric indicia having the structure defined by the claims - i.e., non-numeric indicia designating order of use. As such, the combination of the cited references fail to teach each and every element of the claimed invention as asserted by the Examiner.

In sum, for the reasons set forth above, the claimed invention is taught or suggested in the cited references or elsewhere, thereby precluding a *prima facie* case of obviousness. The cited references, taken alone or in combination, would at least fail to teach non-numeric indicia comprising a computer readable element designating order of use, as recited in claim 40.

Accordingly, Appellant respectfully requests that the rejection of claims 40-41 under 35 U.S.C. §103(a) as obvious be reversed, and claims 40-41 allowed.

VI. The rejection of claims 42 and 43 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong and Martin as applied to claim 40 above, and further in view of U.S. Patent No. 5,923,001 to Morris et al. should be reversed.

Claims 42 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong and Martin as applied to claim 40, in further view of U.S. Patent No. 5,923,001 to Morris (hereinafter "Morris").

Claims 42 and 43 depend from claim 40 and recite that the computer readable element comprises a barcode and recite that the computer readable element is readable by wireless means respectively. Appellant traverses the combination of Chishti, Wong, and Martin, and the corresponding rejection of claim 40, for at least the reasons set forth above.

Morris fails to provide the teachings that are missing from Chishti, Wong, and Martin. While Morris teaches radio frequency identification tags, Morris fails to teach tags, or any other indicia, comprising information designating order of use. In fact, the Examiner merely

alleges that Morris "shows using radio frequency tags to identify items" (Final Office Action, page 8), and does not even allege that the RF tags of Morris include information designating order of use. As such, Morris fails to provide the teachings that are missing from Chishti, Wong, and Martin, and which would be required to teach or suggest each and every element of independent claim 40. Claims 42 and 43 will be allowable at least for depending from allowable independent claim 40.

In sum, for the reasons set forth above, the cited references, taken alone or in combination, would at least fail to teach non-numeric indicia comprising a computer readable element designating order of use, as recited in claim 40, from which claims 42 and 43 depend, or the elements of claims 42 and 43. Accordingly, Appellant respectfully submits that the rejection of claims 42-43 under 35 U.S.C. §103(a) as obvious should be reversed, and claims 42-43 allowed.

VII. The rejection of claims 44 and 47 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong should be reversed.

Claims 44 and 47 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong.

Independent claim 44 reads as follows:

*A system of dental appliances comprising:
a plurality of dental appliances comprising color indicia
designating an order in which each of the plurality are to be worn by a patient to
provide dental treatment, each of the plurality of dental appliances having
cavities shaped to receive and resiliently reposition teeth from one arrangement
to a successive arrangement, wherein the color indicia comprises a dissolvable
dye.*

[Emphasis added].

Independent claim 47 is similar to claim 44, but recites *the color indicia comprises a peel-away wrapper removably attached to the appliance.*

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the element of color indicia designating an order in which each of the plurality are to be worn, e.g., wherein the color indicia comprises a dissolvable dye or a peel-away wrapper, as recited in claims 44 and 47, is not taught or suggested in the cited references of Chishti, and Wong, or anywhere else in the art.

As discussed above in connection the various other pending rejections, Chishti fails to teach non-numeric indicia designating order of use (see above). The cited reference of Wong is overcome for a similar rationale as set forth above with respect to the rejection of claims 38 and 39. In particular, Appellant respectfully disagrees that Wong teach color (i.e., colored handles) to indicate order of usage of orthodontic reamers, as alleged in the Final Office Action, mailed 2/13/07 (page 7). Wong teaches orthodontic reamers with colored handles, but the different colored handles are designed to allow the practitioner to more easily distinguish the differently sized endodontic reamers and avoid confusion between different sized reamers that may be otherwise difficult to distinguish upon visual inspection. No specific starting reamer, final/finishing reamer, or any particular order of use of the tools is prescribed by the color designations or elsewhere in Wong. As such, Wong, taken either alone or in combination with Chishti, fails to teach color as indicia designating an order in which each of a plurality of dental appliances are to be worn, as recited in either claim 44 or claim 47.

Accordingly, Appellant respectfully submits that the rejection of claims 44 and 47 under 35 U.S.C. §103(a) as obvious should be reversed, and claims 44 and 47 allowed.

VIII. The rejection of claims 45 and 46 under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong as applied to claim 44 above, and further in view of Bates et al. (U.S. Patent No. 5,411,295) should be reversed.

Claims 45 and 46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Chishti in view of Wong as applied to claim 44 above, and further in view of U.S. Patent No. 5,411,295 to Bates et al. (hereinafter "Bates").

Claims 45 and 46 depend from claim 44, and further recite that the dissolvable *dye dissolves following removal from a package and contact with air*, and that the dissolvable *dye dissolves following contact with liquid*, respectively.

Appellant respectfully submits that no reasonable combination of the cited references would render the claimed invention obvious. At a minimum, the Office has failed to establish that the element of color indicia comprising a dissolvable dye and used to designate order of use, as recited in claim 44, from which claims 45 and 46 depend, is taught or suggested in the cited references of Chishti, Wong, and Bates, or anywhere else in the art.

The combination of Chishti and Wong is overcome at least for a similar rationale as discussed above in connection with the rejection of claims 38 and 39 - e.g., the cited references, alone or in combination, fail to teach dental appliances or any other structure comprising color indicia designating order of use.

Bates fails to provide the teachings that are missing from Chishti, and Wong. Bates teaches that attempted tampering by means of water immersion will cause the water-soluble graphics to dissolve, thereby exposing the water-insoluble warning indicia. (see, e.g., Bates, col. 1, lines 50-62). Bates does not teach the tamper-evident label or water dissolvable ink, or anything else, as comprising any indicia designating order of use. While it is stated in the Final Office Action 2/13/2007 (page 9) that Bates teaches "indicia", even the Office Action appropriately stops short of alleging that Bates teaches indicia designating order of use. As such, Bates fails to provide the teachings that are missing from Chishti and Wong.

Thus, for the reasons set forth above, the claimed invention is not taught or suggested in the cited references or elsewhere, thereby precluding a *prima facie* case of obviousness. Accordingly, Appellant respectfully request that the rejection of claims 45 and 46 under 35 U.S.C. §103(a) as obvious be reversed, and claims 45 and 46 allowed.

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8. CONCLUSION

For these reasons, it is respectfully submitted that the rejections should be reversed.

Respectfully submitted,



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9. CLAIMS APPENDIX

1. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, and each of the polymeric shells having at least one terminal tooth cavity, wherein the indicia comprises a terminal tooth cavity of differing length in each of the polymeric shells.

2-18. (Canceled)

19. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement;
a framework, wherein each of the plurality of dental appliances are removably attached to a portion of the framework; and
a non-numeric indicia designating an order in which each of the plurality of dental appliances are to be worn by a patient to provide dental treatment.

20. (Original) A system as in claim 19, wherein each of the plurality of dental appliances comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.

21. (Previously presented) A system as in claim 19, wherein the indicia comprises at least one marking on the framework or an appliance indicating the order in which the appliances are to be worn by a patient.

22. - 26. (Canceled)

27. (Previously presented) A package of dental appliances comprising:
a package including a plurality of geometrically distinct dental appliances
positioned in an arrangement within the package which indicates an order of usage, the plurality
of dental appliances comprising a plurality of geometrically distinct successive appliances
having cavities and wherein the cavities of successive appliances have different geometries
shaped to receive and reposition teeth from an initial arrangement toward a successive
arrangement.

28. (Original) A package as in claim 27, wherein each of the appliances
comprises a polymeric shell having cavities shaped to receive and resiliently reposition teeth
from one arrangement to a successive arrangement, the plurality of appliances including a first
shell to be worn by the patient to reposition the teeth from the one arrangement to the successive
arrangement and a second shell to be worn by the patient to reposition the teeth from the
successive arrangement to another successive arrangement.

29. (Previously presented) A package as in claim 28, wherein the
arrangement of appliances within the package comprises stacking of the appliances in an order of
usage.

30-36 (Canceled)

37. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a
non-numeric indicia designating an order in which each of the at least some of the plurality are to
be worn by a patient to provide dental treatment, each of the plurality of dental appliances
comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth
from one arrangement to a successive arrangement, and each of the polymeric shells having a
height, wherein the indicia comprises a different height in each of the polymeric shells.

38. (Previously presented) A system of dental appliances comprising:

a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern.

39. (Previously presented) A system as in claim 38, wherein the cutout comprises a notch in an edge of the appliance.

40. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances comprising a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the indicia comprises a computer readable element.

41. (Previously presented) A system as in claim 40, wherein the computer readable element comprises a barcode.

42. (Previously presented) A system as in claim 40, wherein the computer readable element is readable by wireless means.

43. (Previously presented) A system as in claim 42, wherein the wireless means utilizes radiofrequency.

44. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances comprising color indicia designating an order in which each of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth

from one arrangement to a successive arrangement, wherein the color indicia comprises a dissolvable dye.

45. (Previously presented) The system of claim 44, wherein the dye dissolves following removal of an appliance from a package and contact with air.

46. (Previously presented) The system of claim 44, wherein the dye dissolves following contact with a liquid.

47. (Previously presented) A system of dental appliances comprising:
a plurality of dental appliances comprising color indicia designating an order in which each of the plurality are to be worn by a patient to provide dental treatment, each of the plurality of dental appliances having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein the color indicia comprises a peel-away wrapper removably attached to an appliance.

48. (Previously presented) The system of claim 19, wherein the indicia comprises an arrangement of the appliances on the framework which indicates order of usage.

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10. EVIDENCE APPENDIX

None.

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11. RELATED PROCEEDINGS APPENDIX

None.